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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,268	09/18/2003	Henrik Sonderskov Klint	6279.220-US	7113
7590 12/15/2005			EXAMINER	
Reza Green, Esq. Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,268	KLINT ET AL.	
	Examiner	Art Unit	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/18/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/100,493.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/03, 11/26/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS (PTO-1449) - 10/25/04</u> . |

DETAILED ACTION

Specification

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Calabrese (USPN 4,335,718). Calabrese disclosed a needle cannula with a lumen having the same uniform inside diameter through said needle cannula and where the outside sidewalls tapered towards the skin and wherein there are two portions of the needle cannula with a proximal end and a distal end in a relationship with a peripheral transition zone, and where the proximal end has the same uniform outside diameter, (Figure 3 and entire reference).
2. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al. (USPN 5,868,711). Kramer et al. disclosed a needle cannula with a lumen having the same uniform inside diameter through said needle cannula and where the outside sidewalls tapered towards the skin and wherein there are two portions of the needle cannula with a proximal end and a distal end in relationship with a peripheral transition zone, and where the proximal end has the same uniform outside diameter, (Figure 11 and entire reference).
3. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Barnhart (USPN 2,187,259).

Barnhart discloses a needle cannula with a lumen having the same uniform inside diameter through said needle cannula and where the outside sidewalls tapered towards the skin and wherein there are two portions of the needle cannula with a proximal end and a distal end in relationship with a peripheral transition zone, and where the proximal end has the same uniform outside diameter, (Figure 13, and entire reference).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calabrese.

Calabrese disclosed the claimed invention, but fails to give the specific size and dimensions for the needle's diameter.

Therefore, at the time of the invention, it would have been obvious to construct the device from the claimed dimensions since the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al.

Kramer et al. disclosed the claimed invention except for the size and the dimensions of the outer and inner diameters of the needle.

Therefore, at the time of the invention, it would have been obvious to construct the device from the claimed dimensions since the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative

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dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhart.

Barnhart disclosed the claimed invention except for the size and the dimensions of the outer and inner diameters of the needle.

Therefore, at the time of the invention, it would have been obvious to construct the device from the claimed dimensions since the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
December 12, 2005



NICHOLAS D. LUGGIESI
SOFTWARE PATENT EXAMINER
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